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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,740	07/31/2003	Brigitte Bathe	232234US0X	1392
22850	7590	04/05/2006	EXAMINER	
<b>OBLON, SPIVAK, MCCLELLAND, MAIER &amp; NEUSTADT, P.C.</b> 1940 DUKE STREET ALEXANDRIA, VA 22314				KIM, ALEXANDER D
ART UNIT		PAPER NUMBER		
		1656		

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/630,740	BATH ET AL.	
	Examiner Alexander D. Kim	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 March 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.  
 4a) Of the above claim(s) 13 and 15-21 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-12 and 14 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/23/03, 10/20/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Citrile cycle</u> .                    |

## DETAILED ACTION

### *Application Status*

1. In response to the previous Office Action, a written restriction requirement (mailed on February 9, 2006), Applicants filed an election received on March 13, 2006. Claims 1-21 are pending in the instant Office action.

### *Election*

2. Applicant's election with traverse of Group I, (Claims 1-12 and 14) in the reply filed on March 13, 2006 is acknowledged. Applicant elected species dapA from Claim 4 and citE Claim 5. The traversal is on the ground(s) that the Office has not shown that a burden exists in searching the entire application. This is not found persuasive because each Group represents a distinct independent invention and the search burden exist by the virtue of different class and subclass between distinct inventions. Also, the search for each Group requires different key words because divergent subject matters on application. Searching altogether would create serious search burden on the examination. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21 are pending in the instant application. Claims 13 and 15-21 are withdrawn from consideration as non-elected inventions. Claims 1-12 and 14 will be examined herein.

***Priority***

3. Applicant's claim for the benefit of a prior-filed application 60/401,751 filed 08/08/2002, under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of foreign application 102 35 028.0 (Germany) was received on 31 July 2003.

***Information Disclosure Statement***

4. Information disclosure statements (IDS) filed on October 20, 2003 and December 23, 2003 have been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copies.

***Objections to the Specification***

5. The specification is objected to because the title is not descriptive of the elected claims. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The examiner suggests the following new title, for example:

---Process for the production of L-lysine using Coryneform bacteria sensitive to diaminopimelic acid---

Art Unit: 1656

6. The Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 08.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the chemical used in fermentation (diaminopimelic acid analogues), which implies "new principles" according to applicants and the source species (*Corynebacterium glutamicum*) for completeness.

#### ***Claim Objections***

7. Claim 4 and 5 are objected for containing non-elected subject matter species.

8. Claim 5 is objected to because of the following informalities: The claim 1 contains typographical error in "lysase"; the appropriate spelling is ---lyase---. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-12 and 14 are rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6-9, 11 and 14 recite the limitation "sensitive". There is insufficient antecedent basis for this limitation in the claim. In the instant application, the specification neither cites nor describes the term "sensitive". Clarification is required.

The term "sensitive" in Claims 1, 6-9, 11 and 14 is also a relative term, which renders the claim indefinite. The term "sensitive" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case, the term "sensitive" to diaminopimelic acid can be viewed as either a better growth of bacterium or a reduced growth of bacterium by the presence of diaminopimelic acid in a fermentation medium. If the sensitivity is assumed as a better growth, the term "sensitive" is still indefinite because a bacterium with two times better growth would be considered as non-sensitive compared to a bacterium with two hundred times better growth compared to a one reference bacterium, for example. The relative term "sensitive" without a point of reference, a direction of response and a clear definition makes claims indefinite. Clarification is required.

10. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 3 recite the limitation "the biosynthesis pathway" and "metabolic pathways", respectively. It is unclear if claims 2 and 3 are limited to the one biosynthesis pathway and the one metabolic pathway, respectively, disclosed in the specification (see page 7). Any biosynthesis pathway and any

metabolic pathways are interdependent to each other. Particularly which biosynthetic or metabolic reactions intended to be included in the claimed scope is unclear.

Clarification is required.

11. Claim 4 is rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites the limitation "the gene dapA". There is insufficient antecedent basis for this limitation in the claim. It is unclear if the claims are limited to the one species disclosed in the specification (see page 9) or to any other dapA gene from *E. coli*, *Shigella dysenteriae* or *Helicobacter pylori*, for example.

Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-12 and 14 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a process for the production of L-lysine by fermenting a particular Coryneform bacterium.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at \*23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. (Enzo Biochem 63 USPQ2d 1609 (CAFC 2002)).

The instant specification discloses a process for the increased production of L-lysine by fermenting *Corynebacterium glutamicum* DSM 15662\_Hdap\_r (see pages 13-14). However, the mere disclosure of the single species of *Corynebacterium glutamicum* DSM 15662\_Hdap\_r disclosed does not adequately describe the common structural characteristics of claimed genus of Coryneform bacterium to correlate the structures and functions. The specification does not disclose any prior art to teach a structure and a function of claimed genus of Coryneform bacterium. Moreover, not a single species of claims 6, 8 and 9 are taught.

13. Claims 1-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for producing L-lysine by fermenting *Corynebacterium glutamicum* DSM 15662\_Hdap\_r, does not reasonably provide enablement for producing lysine using any Coryneform bacterium. The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or

unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The nature of invention is drawn to a process for producing L-lysine by fermenting a particular Coryneform, *Corynebacterium glutamicum DSM 15662\_Hdap\_r*, that is resistant to 4-hydroxydiaminopimelic acid. Applicants provide no direction or guidance as to how to make any other *Corynebacterium*, which are resistant to this or other diaminopimelic acid analogues. The instant specification disclose only a single working example of process of L-lysine production using *Corynebacterium glutamicum DSM 15662\_Hdap\_r*, which is resistant to 4-hydroxydiaminopimelic acid, but the breadth of the claims includes using any Coryneform bacterium resistant to diaminopimelic acid analogues to make L-lysine. It is unpredictable to make any Coryneform strain to become resistant to diaminopimelic acid analogues.

The invention the Examiner has described as being enabled appears to employ novel biological material, specifically *Corynebacterium glutamicum DSM 15662\_Hdap\_r*. Since the biological material are essential to such an invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 USC 112 §1<sup>st</sup> may be satisfied by a deposit of the biological materials.

The specification disclose that applicants have deposited the biological materials (*Corynebacterium glutamicum DSM 15662\_Hdap\_r*) according to the Budapest Treaty.

The following requirement has to be satisfied: An affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific of record over his or her signature and registration number, stating that the specific biological materials will be irrevocable and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Applicant's attention is directed to MPEP section 2400 in general, and specifically to 2411.05, as well as to 37 CFR 1.809(d), wherein it is et forth that "the specification shall contain the accession number for the deposit, the date of the deposit, "the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification could be amended to include this information, however, applicant is cautioned to avoid entry of new matter into the specification by adding any other information.

14. Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for over-expression of a gene(s) from L-lysine biosynthesis pathways, does not reasonably provide enablement for making "enzyme or protein having a high activity (see page 7 line 29)". The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* above.

The nature of the invention is drawn to a process of producing L-lysine from the fermentation of the *Corynebacterium glutamicum* with a higher activity of enzyme(s) encoded from the L-lysine biosynthetic pathway gene(s). The prior art teaches the activity of enzyme can be increased by a certain mutation within a residue(s) of protein. However, whether increase or decrease of enzyme activity from any mutation is unpredictable. The specification does not disclose any directions or guidances on how to increase a certain enzyme's activity involved the L-lysine biosynthesis (Claim 2) and dihydrodipicolinate synthase (Claim 4). No single working example of an enzyme with increased activity is disclosed in the instant specification. The breadth of the claim disclose a enhancement by increasing protein activity from glycolysis, anaplerosis, citric acid cycle, pentose phosphate cycle, amino acid export and regulatory proteins (see page 7) as well as a dihydrodipicolinate synthase (Claim 4). However, the enablement requirement disclosed in the specification does not describe full scope of the claim. The number of experimentation required for increasing catalytic activity of a protein is high due to the unpredictable nature of protein mutagenesis. For all of the above reason, it would require undue experimentation necessary for one skilled in the art to practice the full scope of the claimed methods.

15. Claims 5 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for reduction or elimination of citE expression, does not reasonably provide enablement for making "enzyme with a low activity (see page 10 line 3)". The specification does not enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* above.

The nature of the invention is drawn to a process of producing L-lysine from the *Corynebacterium glutamicum* with attenuated citE gene by reducing catalytic activity of citrate lyase. The prior art teaches the activity of enzyme can be lowered by a certain mutation within an enzyme residue(s). However, it has been known that the decrease of enzyme activity is unpredictable. The specification does not disclose any directions or guidances on how to make a low activity enzyme. No single working example of enzyme with reduced catalytic activity is disclosed in the instant specification. The breadth of the claim disclose a gene(s) attenuation by decreasing protein activity from citE (Claim 5). However, the enablement requirement disclosed in the specification does not describe full scope of the claim. The number of experimentation required for decreasing activity of a protein is high due to the unpredictable nature of protein mutagenesis. For all of the above reason, it would require undue experimentation necessary for one skilled in the art to practice the full scope of the claimed methods.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1656

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1-12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Bathe et al. (USPAP 2004/0067561 filed on 30 Jul. 2003 as cited in IDS). The examiner notes that the instant claims cannot be afforded the earlier effective filing dates of priority documents because the translations of said documents have not been provided. The instant claims are drawn to a process for the production of L-lysine using Coryneform bacterium resistant to diaminopimelic acid analogues with additional enhancement of dapA or attenuation of citE.

Bathe et al. teach a process for the production of L-lysine by fermenting Coryneform bacterium sensitive to diaminopimelic acid analogues including 4-fluorodiaminopimelic acid, 4-hydorxydiaminopimelic acid, 4-oxo-diaminopimelic acid and/or 2, 4, 6-triaminopimelic acid (p. 3 line 22 – p. 4 line 3). Bathe et al. also teach additional limitations to the above process for the production of L-lysine; a enhancement of a gene(s) of the L-lysine biosynthetic pathway (specifically dapA), a attenuation of L-lysine metabolic pathways (specifically citE) and a use of a mutant Coryneform bacterium (p. 8 line 5 – p. 9 line 26). Thus, Bathe et al. teach a process that meets all limitation of the instant claims.

Art Unit: 1656

17. Claims 1, 6-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sano et al. (US Patent 4,861,722; issued on 29 Aug. 1989). The instant claims are drawn to a process for the production of L-lysine by fermenting Coryneform bacterium sensitive to diaminopimelic acid analogues with additional limitations by dependent claims (Claims 6-12 and 14).

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The broadest reasonable interpretation of analogue, in the absence of a clear definition or limitation provided by the specification, is any chemical with common basic structure and diaminopimelic acid analogues do not exclude diaminopimelic acid with all common structural features. Sano et al. teach an increase in production of L-lysine by fermenting *Brevibacterium lactofermentum* ATCC 39134 (Example 1) and *Corynebacterium glutamicum* ATCC 13287 (Example 2) transformed with an expression vector carrying a diaminopimelic acid decarboxylase gene, which host cells are inherently resistant to a diaminopimelic acid, because any adverse growth effects from diaminopimelic acid will be reduced by decarboxylation of diaminopimelic acid due to the excess enzyme expressed from the vector. It is also reasonable that the transformant of Sano et al. be resistant to other diaminopimelic acid analogues including 4-fluorodiaminopimelic acid, 4-hydroxydiaminopimelic acid, 4-oxodiaminopimelic acid and 2, 4, 6-triaminopimelic acid because a common structure responsible for any adverse effects on cell growth would be also recognized by diaminopimelic acid decarboxylase.

Claim 14 has additional limitation "a mutant" of a Coryneform bacterium. Sano et al. also meet this limitation because a transformant used by Sano et al. is a mutant,

"homoserine auxotroph ---- mutant" (see column 7 line 65 – column 8 line1), and resistant to diaminopimelic acid analogues as described above. Thus, Sano et al. teach processes that meet all the limitation of the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (US Patent 4,861,722; issued on 29 Aug. 1989).

Sano et al teach as described above. Sano et al. also teach that "the dapA gene (encoding dihydridopicolinate synthetase) lead to an increase in lysine production; this reaction is the limiting biosynthetic step in lysine overproducers" (see 2<sup>nd</sup> column, line 52-55). While Sano et al. does not expressly teach the combination, Sano et al. "suggest that such a method of gene amplification could be used to improve strains which overproduce metabolites" (see 2<sup>nd</sup> column, line 56-59). The dapA gene cited by Sano et al. meets the limitation of "at least one gene of the biosynthesis pathway of L-lysine" in the instant Claim 2, additional to the instant Claim 4, because the dapA gene is a part of L-lysine biosynthesis pathway (see Scheme I, Sano et al., 1989).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to overexpress the dapA gene as taught by Sano et al. with the overexpression of diaminopimelic acid decarboxylase because Sano et al. specifically suggest it. Moreover, one would have been motivated to do so because both processes taken separately increase L-lysine production and L-lysine is useful "as a feedstuff" (see column 1, line 17). The invention taken as a whole is *prima facie* obvious.

19. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (US Patent 4,861,722; issued on 29 Aug. 1989) in view of Farwick et al. (US Patent Application Pub. No: US 2003/0113879 A1; filed on June 6, 2001).

Sano et al. teach as described above. Sano et al. do not teach attenuation of the citE gene.

Farwick et al. teach a process of increased production of L-lysine from Coryneform bacterium (see Example 5, Table 1) by "the citE gene is present in attenuated form", which meets the limitation of the Claim 5.

The citE also meets the limitation of a Claim 3 of attenuating a gene(s) in L-lysine metabolic pathways because the citrate lyase encoded by citE that is a part of L-lysine metabolic pathway. The L-lysine degrades into Acetyl-CoA which turns into citrate as indicated in the Citrate cycle (see attachment).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Coryneform bacterium of Sano et al. by additionally attenuating the citE gene as suggested by Farwick et al. with a reasonable

expectation of success. The motivation to do so is provided by Farwick et al. who teach the usefulness of attenuating a *citE* gene to increase the production of L-lysine in Coryneform bacterium because the L-lysine is useful "in human medicine and in the pharmaceuticals industry, in the foodstuffs industry and, very especially, in the feeding of animals" (see Farwick et al., p2, §0002). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

20. Claims 1-12 and 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 and 14 of copending Application No. 10/629,551. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Conclusion***

21. Claims 1-12 and 14 are rejected for the reasons identified in the numbered sections of the Office Action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim  
29 February 2006

  
KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER